

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

RANDALL HIX, *et al.*,

Plaintiffs,

Case No. 3:18-cv-00437-RCJ-WGC

ZIMMER BIOMET HOLDINGS, INC. 21-11

Defendants

ORDER

In 2010, Randall Hix had an artificial hip replacement using a Biomet M2a Magnum implant. Hix and his wife, Liana Hix, brought this suit against Defendants Zimmer Biomet Holdings, Inc., Biomet, Inc., Biomet Orthopedics, LLC, and Biomet U.S. Reconstruction, LLC, (collectively “Biomet”) alleging the artificial hip device was defective. (Amended Complaint, ECF No. 201). Presently before the Court is Biomet’s motion to exclude Jeffrey F. Shapiro, M.D., one of Hix’s case-specific experts (ECF No. 276). Hix opposes the motion. (ECF No. 285).

I. PROCEDURAL HISTORY

On October 2, 2012, the Judicial Panel on Multidistrict Litigation transferred the first actions regarding Biomet M2a Magnum hip implants to the Northern District of Indiana as the Biomet M2a Magnum Hip Implants Products Liability multi-district litigation, MDL Case No. 3-12-md-2391. In February 2013, the MDL court entered an order allowing parties to file new actions directly into the MDL action. In March 2014, Hix initiated this action by filing a complaint in the Biomet M2a Magnum MDL. Following consolidated pre-trial proceedings primarily directed to common-issue

1 discovery and to some case-specific discovery, the MDL court transferred this matter to the District
 2 of Nevada in September 2018.

3 **II. BACKGROUND**

4 On July 12, 2010, Hix (then 36 years old) had a total hip arthroplasty (THA, i.e., joint
 5 replacement) performed by Dr. Richard Mullins. Dr. Mullins implanted the Biomet M2a Magnum
 6 metal-on-metal (MoM) artificial hip device.

7 Prior to the THA procedure, Hix had surgery in 1997 on his left hip due to a Slipped Capital
 8 Femoral Epiphysis when he was 13 years old.

9 In 2008, Hix began experiencing pain in his left hip that worsened over time. In March 2010,
 10 Hix was arthroscopically treated for left hip femoroacetabular impingement. When the procedure
 11 did not resolve Hix's pain, he was referred to Dr. Mullins, who recommended a total left hip
 12 replacement. Hix and Dr. Mullins met with a Biomet sales representative who demonstrated
 13 Biomet's sample hip prosthetics. Dr. Mullins thought that a metal-on-metal device would provide
 14 Hix a better quality of life – and would last longer – than a metal-on-polyethylene device. Hix
 15 decided to have the M2a Magnum MoM device implanted.

16 Following the THA procedure, Hix began again experiencing pain in his left hip in March
 17 2012. He saw Dr. Suzanne Zsikla, who referred Hix to Dr. Richard Blakey, an orthopedic surgeon.
 18 Hix saw Dr. Blakey in August 2012. A radiograph was taken, showing the MoM implant with
 19 reactive bone at the end of the stem. A presumptive diagnosis of metallosis¹ was made.

20 A bone scan performed on September 5, 2012, indicated Hix's hip was normal and did not
 21 indicate an abnormal uptake. On September 11, 2012, Dr. Blakey indicated he was fairly certain
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24 ¹ In his deposition, Hix's treating physician, Dr. Blakey, described metallosis as an inflammatory
 reaction to the wear product of an MoM device.

1 Hix did not have an infection and recommended a revision of the Biomet M2a Magnum MoM hip
2 device.

3 Dr. Blakey performed the revision surgery on Hix's left hip on October 31, 2012. Dr. Blakey
4 removed the Biomet acetabular cup and replaced it with a Zimmer metal-on-polyethylene
5 constrained hip construct. He also removed damaged tissue and implanted a constrained liner to
6 reduce the chance of dislocation or subluxation. Dr. Tony Yang examined the removed tissues for
7 pathology and noted chronic inflammation, reactive hyperplasia, and pigmented macrophages
8 containing a grayish pigment consistent with foreign material. Dr. Blakey's post-operative diagnosis
9 noted painful left metal-on-metal total hip secondary to metallosis.

10 Two weeks after this surgery, Hix had an MRI of his lumbar spine, which showed an L5-S1
11 right-sided paracentral disc protrusion causing mild stenosis of the right neural foramina.

12 On January 10, 2013, Hix was seen by Dr. Blakey as Hix had "developed some cellulitis
13 about the left hip wound." Dr. Blakey informed Hix that he might need to aspirate the hip. This
14 procedure was performed on January 24, but produced "little fluid, if any." Cultures on the fluid
15 were negative for infection. Hix was continuing to have pain when he had an office visit with Dr.
16 Blakey in June 2013. Dr. Blakey "talked to [Hix] about the fact that sometimes the metallosis
17 reaction comes back even though we have revised the hip." Dr. Blakey performed another left-hip
18 aspiration in August 2013 and gave Hix a steroid injection.

19 Hix had a follow-up visit a week later. Dr. Blakey recorded in his notes: "I suspect that he
20 is having continued inflammation, possibly from the metallosis." Following an office visit two
21 weeks later, Dr. Blakey noted there was not much else he could do for Hix's pain.

22 Hix continued to have pain through 2014. In November 2014, Hix saw Dr. Martin Arraiz,
23 who noted radiculitis (pain radiating along a nerve resulting from inflammation at the root of the
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1 nerve connecting to the spine) in the lower left extremity. Hix received an epidural injection in
2 December 2014.

3 Hix saw Dr. Blakey in January 2015. Dr. Blakey noted Hix “is actually getting better with
4 respect to his left hip. He is still having pain.” Following a July 2015 office visit, Dr. Blakey noted
5 “Hix has had increasing pain in his left hip revision last month.”

6 On October 21, 2017, Hix went to the emergency room the day following “kicking an object
7 . . . with his left leg” that resulted in “sudden onset pain left hip.” The emergency doctor noted a
8 final impression of “[p]ain of left hip joint” and “[d]islocation of left hip.”

9 Two days later, Dr. Chad Watts performed a revision surgery on Hix’s left hip for “failed
10 constrained liner with dislocation of left total hip.” Dr. Watts removed the cup with constrained
11 liner and replaced it with a “62 Biomet OsseoTi shell with dual mobility liner” and “2B +6 revision
12 ceramic head with a titanium sleeve.” Dr. Watts notes indicate that Hix “was very scarred in and
13 had a pretty stiff hip. There was some metal staining from his prior metallosis, but overall the muscle
14 and tissues were in reasonable shape.” He further noted the “constrained liner was broken – there
15 had clearly been chronic impingement which led to failure.”

16 Four weeks after the surgery, Hix visited the emergency room with “pain to the surgical site,
17 redness, and drainage around surgical incision associated with fever (102.0 deg F) and chills.” Hix
18 underwent surgery the following day to open the surgical wound for “drainage with debridement
19 and placement of wound VAC.” Two days later, Dr. Robert Crouse performed another surgery. As
20 Hix had “an obvious deep infection,” Dr. Crouse removed the artificial hip devices, removed infected
21 material for biopsy and culture, and performed a femoral osteotomy. Dr. Crouse further placed an
22 antibiotic impregnated cement spacer in the acetabulum, the location of the infection. The material
23 removed for culture showed growth for *Staphylococcus lugdunensis*, with 1 of 3 cultures showing

1 growth for Methicillin-Resistant Staphylococcus aureus. Hix remained on IV antibiotics for six
2 weeks.

3 On February 8, 2018, Dr. Watts implanted an artificial hip consisting of a Stryker Restoration
4 cup and stem with a ceramic head and cable.

5 Hix had an office visit with Dr. Ali Nairizi in June 2018 for pain management. Over the
6 following year, Hix underwent a femoral nerve block, lumbar sympathetic nerve block, and SI joint
7 injections with corticosteroids for pain.

8 In September 2019, Dr. Denis Patterson implanted a temporary dorsal root ganglion spinal
9 cord stimulator for pain management and implanted a permanent stimulator the next month.

10 In November, Hix had an office visit with Dr. Watts, reporting a significant increase in pain
11 and redness and swelling around the left hip. Dr. Watts recorded the impression of “[l]ikely infected
12 left hip replacement.” Dr. Watts aspirated the left hip. A culture of the withdrawn material indicated
13 a streptococcus viridans infection. Hix underwent surgery on his left hip the following day, with
14 Dr. Watts performing a tissue debridement and irrigation, and exchanging the MDM liner, the
15 ceramic head and MDM head. On December 1, 2019, Dr. Watts performed another debridement
16 and irrigation of the hip. Hix was hospitalized for the infected left hip from November 22, through
17 December 11, 2019.

18 In May 2020, Dr. Patterson exchanged the implantable power generator for the nerve
19 stimulator.

20 **III. LEGAL STANDARDS**

21 **A. Admissibility of Expert Testimony**

22 Federal Rule of Evidence 702 governs the admission of expert testimony and provides that
23 if a witness is qualified as an expert by knowledge, skill, experience, training, or education, the
24 witness can provide opinion testimony so long as:

- 1 (a) the expert's scientific, technical, or other specialized knowledge will help the
2 trier of fact to understand the evidence or to determine a fact in issue;
3 (b) the testimony is based on sufficient facts or data;
4 (c) the testimony is the product of reliable principles and methods; and
5 (d) the expert has reliably applied the principles and methods to the facts of the
6 case.

7 Fed. R. Evid. 702.

8 The task of the trial court is to “assure that the expert testimony ‘both rests on a reliable
9 foundation and is relevant to the task at hand.’” *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010)
10 quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). This task applies to all
11 expert testimony governed by Rule 702. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-148
12 (1999). Rule 702 “is premised on an assumption that the expert's opinion will have a reliable basis
13 in the knowledge and experience of [the relevant] discipline.” *Daubert*, 509 U.S. at 592. The party
14 offering the expert witness “has the burden of establishing that the pertinent admissibility
15 requirements are met by a preponderance of the evidence.” Fed. R. Evid. 702 Advisory Committee
Notes.

16 “[M]any factors will bear on the inquiry.” *Daubert*, 509 U.S. at 593. In considering the
17 admissibility of scientific expert testimony, the Supreme Court generally noted four factors while
18 acknowledging that it was not setting “out a definitive checklist or test.” *Id.* As summarized by the
19 Ninth Circuit, a court may consider: “1) whether the theory can be or has been tested; (2) whether
20 the theory has been subjected to peer review and publication; (3) the known or potential rate of error
21 and the existence of standards controlling a technique’s operation; and (4) whether or not the theory
22 is generally accepted.” *United States v. Hankey*, 203 F.3d 1160, 1167 (9th Cir. 2000). However,
23 these factors “may or may not be pertinent in assessing reliability, depending on the nature of the
24 issue, the expert's particular expertise, and the subject of his testimony.” *Kumho*, 526 U.S. at 150.

1 Ultimately, the court must “make certain that an expert, whether basing testimony upon professional
2 studies or personal experience, employs in the courtroom the same level of intellectual rigor that
3 characterizes the practice of an expert in the relevant field.” *Id.* at 152.

4 **IV. DISCUSSION**

5 **A. Failure to Warn Opinions**

6 Biomet seeks to exclude Dr. Shapiro’s opinions that Biomet failed to adequately warn Dr.
7 Mullins and Hix of the risks of the M2a Magnum device.

8 Dr. Shapiro states, in his supplemental report, that: “Biomet failed to provide Dr. Mullins
9 and Mr. Hix with proper warnings of the risks of using metal-on-metal implants. Biomet’s literature,
10 such as the patient package insert and/or Surgical Technique brochures did not provide adequate
11 warning of the known risks associated with the M2A metal-on-metal hip implants.” He further states
12 that Biomet internally acknowledged “the failure modes of metal-on-metal devices and documented
13 the different biologic risks due to cobalt and chromium metal debris” but that “this information was
14 either not or not properly relayed directly to Mr. Hix when he met with the representatives nor to
15 Dr. Mullins.”

16 Biomet argues that Dr. Shapiro is not qualified to opine on the adequacy of Biomet’s
17 warnings regarding the medical device because he lacks regulatory or warning drafting experience.
18 The Court agrees. To the extent that Hix seeks to offer Dr. Shapiro’s testimony regarding the
19 adequacy of Biomet’s regulatory warnings, that is, whether certain information should or should not
20 have been included in the regulated warnings, Hix has not shown that Dr. Shapiro is qualified to
21 offer such testimony. The Court would note, however, that in granting Biomet’s motion, the Court
22 does so only to the extent that Biomet has established that Dr. Shapiro is not qualified in the
23 regulatory process regarding warnings accompanying medical devices. That lack of expertise does
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1 not, of itself, establish that Dr. Shapiro cannot offer expert testimony as a surgeon regarding the
2 substance of Biomet's warnings and communications to Hix and his doctor.

3 **B. Pain Management**

4 Biomet asserts that Dr. Shapiro is not qualified to offer an opinion on pain management. Hix
5 effectively agrees but notes that "it is not necessary for Dr. Shapiro to be qualified as a pain
6 management specialist in order to assess a patient's hip pain." Accordingly, the Court will preclude
7 Dr. Shapiro from providing expert testimony on pain management. The Court notes, however, that
8 Dr. Shapiro's lack of expertise in pain management does not preclude Dr. Shapiro from offering
9 expert opinion on the causes of Hix's hip pain.

10 **C. Causation of Left Hip Pain**

11 Biomet argues that Dr. Shapiro's opinions regarding causation of pain should be excluded
12 because he failed to conduct a differential diagnosis with reasonable diligence. The Court disagrees.
13 *Daubert* requires only that an expert's opinion has "a reliable basis in the knowledge and experience
14 of [the relevant] discipline," *Daubert*, 509 U.S. at 592, not an unassailable basis for that opinion.
15 Biomet's arguments – that Dr. Shapiro distinguished between buttock and leg pain (lumbar spine)
16 versus groin and thigh pain (hip implant) and failed to consider the impact of Hix's use of opioids
17 on Hix's perception of pain – go to the weight not the admissibility of Dr. Shapiro's expert opinions
18 on causation. The Court will not preclude Dr. Shapiro from offering expert opinion on the causation
19 of Hix's hip pain.

20 **D. Significant Permanent Damage of Left Hip**

21 Biomet argues that Dr. Shapiro's opinion that the M2a Magnum device caused significant
22 permanent damage to Hix's left hip should be excluded because Dr. Shapiro did not physically
23 examine Hix (but examined him by videoconference) and because Dr. Shapiro determined that Hix
24 had a reduced range of motion in his lumbar spine but reasonable range of motion in his hips. These

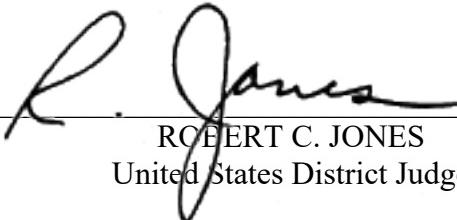
1 arguments do not establish that Dr. Shapiro's opinion is inadmissible as unreliable. Rather, the
2 arguments concern issues appropriate to the weight of Dr. Shapiro's opinions. The Court will not
3 preclude Dr. Shapiro from offering expert opinion regarding whether Hix suffered permanent
4 damage to his left hip.

5 **CONCLUSION**

6 IT IS HEREBY ORDERED that the Motion in Limine to Exclude Plaintiff's Case-Specific
7 Expert Jeffrey F. Shapiro, M.D. brought by Zimmer Biomet Holdings, Inc., Biomet, Inc., Biomet
8 Orthopedics, LLC, and Biomet U.S. Reconstruction, LLC. (ECF No. 276) is GRANTED in part
9 and DENIED in part as set forth above.

10 IT IS SO ORDERED.

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12 Dated: March 29, 2022

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15 ROBERT C. JONES
United States District Judge
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